

REMARKS

Reconsideration is requested.

Claims 1-38 have been canceled, without prejudice. Claims 39-44 have been added, to advance prosecution. No new matter has been added. Support for the claims are submitted to be found throughout the specification.

The Section 112, first paragraph, rejection of claims 32-38 stated on pages 2-4 of the Office Action dated January 6, 2004, is traversed in the event the above amendments are not entered. In the event the above amendments are entered, the claims are submitted to be supported by an enabling disclosure. Consideration of the following in this regard is requested.

Initially, the Applicants note that the claims are written in a manner which will be understood by one of ordinary skill in the art who will be capable of practicing the claimed invention without undue experimentation. Specifically, the Applicants submit that the previously cited scientific literature describes administration of antibody therapies in as broad a manner as is presently claimed. Moreover, by the Examiner's reasoning, the Patent Office would not grant improvement patents wherein methods, such as those involving antibody therapy, are utilized by further developed novel inventions. The Examiner's position is contrary to the nature and purpose of the patent system.

The concerns of the Examiner with regard to "delivery route of a protein or an antibody, the amount and stability of the protein or antibody present at the targeted site, and the uptake of the protein or antibody by the targeted cells and its activity within the targeted cells" (see, page 3 of the Office Action dated January 6, 2004), are, as stated

by the Examiner, "all important factors". The Applicants submit however that such factors, to the extent required, are the subject of further experimentation which will not require an undue effort for one of ordinary skill in the art. The Examiner has not established that such factors are required to practice the invention or that, to the extent they may be required, undue experimentation would be required to obtain any further required aspect of the claimed method. The Applicants have provided a well-reasoned response to the Examiner's previous objections, in their Amendment of October 30, 2003, and the Examiner has, with due respect, not responded by disagreement or further arguments indicating any error in the Applicants' reasoning. The Examiner's apparent requirement for clinical trials, or something more, is not required by the Patent Law for demonstrating enablement and the evidence of record as well as the generally advance level skill in the art are submitted to be sufficient to establish that the presently claimed invention is supported by an enabling disclosure.

The claims have been further amended above in response to the Examiner's comments on page 4 of the Office Action of January 6, 2004, and to further emphasize that the presently disclosed invention provides a two-part drug delivery system that is useful for targeted delivery of suitable compounds according to a disorder to be treated. Entry of the above amendments and/or withdrawal of the Section 112, first paragraph, rejection of claims 32-38 are requested.

The Section 102 rejection of claim 32 over Flickinger (1976, European Journal Cancer, Vol. 12, pages 159-160), is traversed in the event the above amendments are not entered. The amended claims are submitted to be patentable over Flickinger and consideration of the following in this regard is requested.


The Examiner is urged to appreciate that claim 32 provides an antibody conjugated to a lipase which is one part of a two-part enzymatic system that is only active, for example, after it reaches its desired site of action and is reconstituted by a second lipase component. The claims have been amended above to further clarify this aspect of the presently claimed invention. The amendment was not previously presented as the Examiner's previous comments interpreting claim 32 did not emphasize the word "or" as emphasized on page 5 of the Office Action of January 6, 2004. While the Applicants do not agree with the Examiner's interpretation of claim 32, it is only after this emphasized comments in the Office Action of January 6, 2004, that the Applicants have been able to fully appreciate the Examiner's concerns and interpretation of claim 32. The claims have been amended above, without prejudice, to advance prosecution and entry of the amendments and allowance of the amended claims are requested.

The Examiner is requested to contact the undersigned if anything further is required in this regard.

Respectfully submitted,

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